



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

7477 10-11-7 1972

NOV - 8 2004

Mr. Terrence Lemerond
President
EuroPharma, Inc.
P.O. Box 22547
955 Challenger Drive
Green Bay, Wisconsin 54305-2547

Dear Mr. Lemerond:

This is in response to your letter of October 14, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that EuroPharma, Inc. is making the following claims, among others, for the product **LitoZin™** :

“Supporting the body’s natural defense against inflammation;”
“These organic nutrients work with the body’s own anti-inflammatory systems to preserve joint function;”
“Most sufferers experience noticeable improvement in joint performance in three weeks or less.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to prevent or treat disease because they imply that the product is intended to treat arthritis. Arthritis is defined as “Inflammation of a joint or a state characterized by inflammation of joints.” Stedman’s Medical Dictionary, 26th Edition. The claims for the product unambiguously describe its intended use for persons with (i.e., “sufferers”) inflammatory joint conditions because it is for “defense against inflammation,” “work with the body’s own anti-inflammatory systems to preserve joint function” and “improvement in joint performance. Taken together, these claims evidence that the product is intended for use in the diagnosis, mitigation, treatment, cure, or prevention of a specific disease, namely, arthritis. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the

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Page 2 - Mr. Terrence Lemerond

meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

for Robert Moore

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

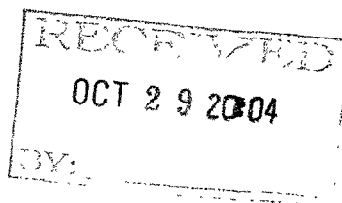
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Minneapolis District Office, Office of Compliance, HFR-CE840

EuroPharma.

10/14/04

Office of Nutritional Products Labeling
and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740



Re: Notification for Statement on Dietary Supplement Labels

Dear Sir/Madam:

This notification is being submitted on behalf of EuroPharma, Inc., Green Bay, Wisconsin, a distributor of dietary supplement products.

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343(r)(6), and in accordance with the authorized provisions of 21 CFR § 101.93(a), your Agency is hereby notified that EuroPharma, Inc. has made statements of "nutritional support", as described in 21 U.S.C. § 343(r)(6)(A), for its dietary supplement(s) as follows:

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>
LitoZin™	Promotes joint health, mobility and comfort Protects the integrity of cartilage and promotes joint health and comfort Joint support and antioxidant properties Supports healthy C-reactive protein levels Supporting the body's natural defense against inflammation These organic nutrients work with the body's own anti-inflammatory systems to preserve joint function Most sufferers experience noticeable improvement in joint performance in three weeks or less

As required, enclosed are two photocopies of this notification.

The undersigned certifies on behalf of EuroPharma, Inc. that the information presented and contained in this correspondence is complete and accurate.

Sincerely yours,
EuroPharma, Inc.

By: Terrence Lemerond
Its: President

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